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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/508,445	09/16/2004	Joseph P Orban III	2786	6710

7590 08/14/2008
Covidien
60 Middletown Avenue
North Haven, CT 06473

EXAMINER

SMITH, FANGEMONIQUE A

ART UNIT	PAPER NUMBER
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3736

MAIL DATE	DELIVERY MODE
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08/14/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/508,445	Applicant(s) ORBAN, JOSEPH P	
	Examiner FANGEMONIQUE SMITH	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 March 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Office Action is responsive to the Amendment filed on March 3, 2008. The Examiner acknowledges the amendment of claims 1, 19, 21, 28 and 31; and the addition of claims 33-35. Claims 1-35 are pending.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-5, 7-9 and 12-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cochran et al. (U.S. Patent Number 5,215,521) in view of Kammerer et al. (U.S. Patent Number 5,480,404) and in further view of Pagedas (U.S. Patent Number 6,387,102).

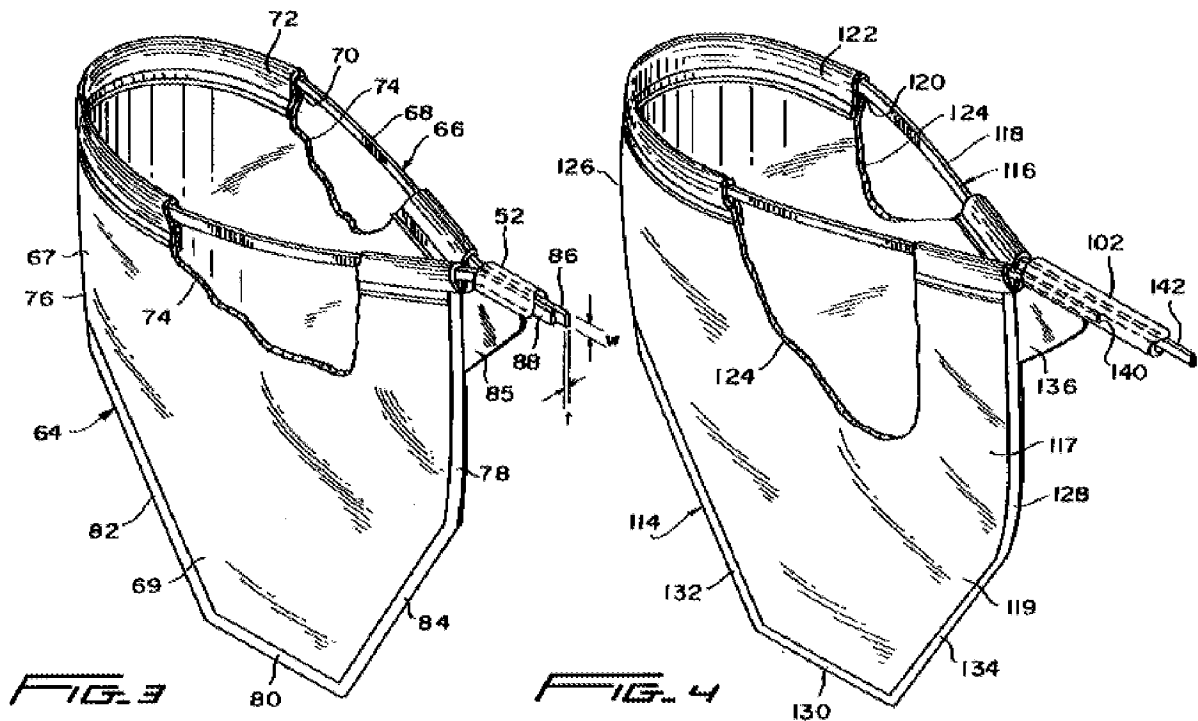
In regard to claims 1-5, 7-9, 12, 13, 30 and 31, Cochran discloses a tissue removal device and method comprising an elongate shaft (26) having a distal end and a proximal end, wherein the elongate shaft defines a longitudinal axis. Cochran et al. further disclose a bag support (26) defining an opening, the bag support being collapsible and expandable to open and close the opening. The device includes the bag (22) operatively connected to the bag support. The bag (22) has an open first end operatively secured to the bag support and a closed end. The bag support in a collapsed position, substantially closes the first end of the bag. Cochran et al. disclose a tube (16) for receiving the shaft, bag support and bag. The Cochran et al. device has

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folds approximately parallel with the longitudinal axis as shown in Figure 3. The bag assembly includes a sheath (20) disposed about the bag assembly and the sheath is formed of a plastic lattice construction, which is inherently capable of having a weakness for breaking away from the bag (col. 9, lines 40-50). Cochran et al. additionally disclose an actuation system operatively connected to the sheath in order to facilitate removal of the sheath from the bag assembly (col. 10, lines 28-35). The actuation system includes a tear line formed in the sheath to facilitate tearing of the sheath (Col. 10, lines 1-5 and 28-35). Also included with the actuation member is an expandable member (24, 26) positioned within the bag assembly. The expandable member is initiated remotely from the bag. In regard to claims 14-29 and 32, Cochran et al. disclose a tissue removal device wherein the bag (22) is conical in shape and has a proximal edge and a distal edge. The bag includes a slot formed in the vicinity of the bag support near the proximal edge to enable the diameter of the bag to be adjusted. The device disclosed by Cochran et al. further includes a control line (26). Upon use, the Cochran et al. device includes method steps of folding the bag such that the proximal edge is capable of crossing the distal edge (Fig.3) and the folds are approximately parallel to the longitudinal axis. Use of the Cochran et al. device further includes method steps of closing the upper end of the bag using the support, transforming the bag from an open to a closed position. The bag is folded onto itself and the folded bag is placed into a sheath. Cochran et al. disclose the features of the Applicant's invention as described above. Although the Cochran et al. device is capable of folding transversely, Cochran et al. do not specifically disclose this feature. Kammerer et al. disclose a surgical tissue retrieval instrument having a bag having at least one transverse fold. The device disclosed by Kammerer et al. includes a pouch having a trapezoidal shape for the collection and removal of tissue samples.

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The pouch includes a first and second edge with bag folds including at least one transverse fold extending from the first edge toward the second edge such that an angle less than 90 degrees is defined relative to the longitudinal axis (Figures 3 and 4).



Although the combined references of Cochran et al. and Kammerer et al. disclose the features of the Applicant's invention as described above, the combination does not specifically disclose the bag being folded onto itself when collapsed into a folded position. Pagedas discloses a reusable surgical device for retrieving a mass during a surgical procedure. The device disclosed by Pagedas includes a wand (12) with a rod (18) attachment, and a bag (50) connected to the rod (18) and wand (12) assembly. The bag (50) extends away from the wand when in an unfolded position and folds onto itself in a folded position as shown in Figures 17 and 18 below.

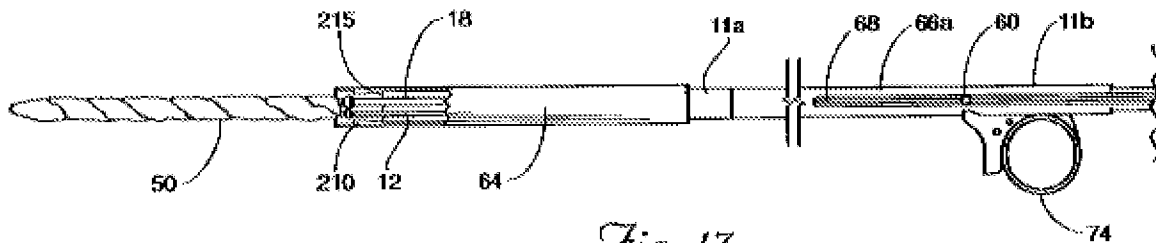


Fig. 17

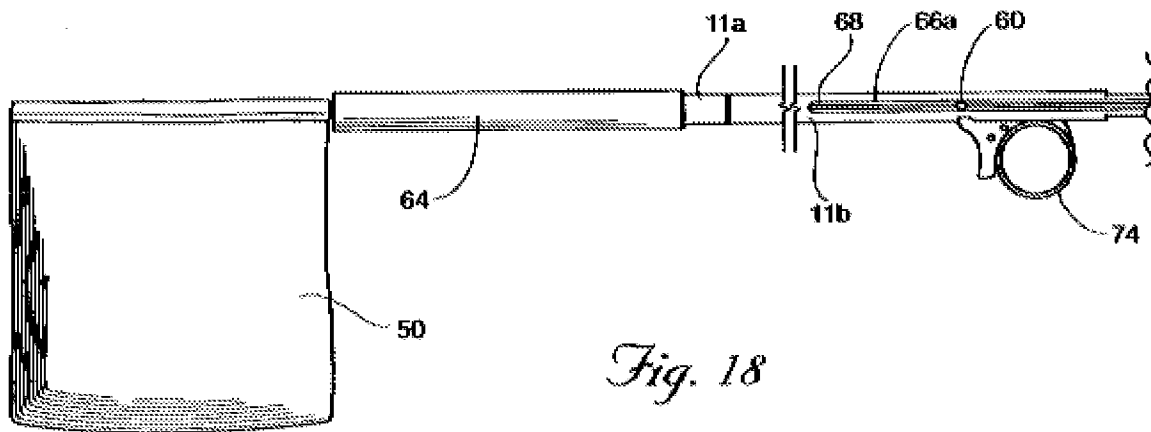


Fig. 18

It would have been obvious to one having ordinary skill in the art at the time the Applicants' invention was made to modify a tissue removal device and method comprising an elongate shaft, similar to that disclosed by the combined references of Cochran et al. and Kammerer et al., to include a bag which folds onto itself, similar to that disclosed by Pagedas, to permit the bag to easily extend through a port to the target site (col. 8, lines 63-67; col. 9, lines 1-13).

4. Claims 1, 4 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pagedas (U.S. Patent Number 6,387,102) in view of Summer (U.S. Patent Number 5,899,694).

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In regard to claims 1, 4 and 6, Pagedas disclose a reusable surgical device for retrieving a mass during a surgical procedure comprising an elongated shaft wand (12) with a rod (18) attachment, and a bag (50) connected to the rod (18) and wand (12) assembly. The bag (50) extends away from the wand when in an unfolded position and folds onto itself in a folded position. The elongate shaft (12) has a distal end and a proximal end, wherein the elongate shaft defines a longitudinal axis. Pagedas further discloses a handle connected to a flexible bag support (22) defining an opening, the bag support (22) being collapsible and expandable to open and close the opening. The device includes the bag (50) operatively connected to the bag support. The bag (50) has an open first end operatively secured to the bag support and a closed end. The bag support in a collapsed position substantially closes the first end of the bag. The Pagedas device has folds approximately parallel with the longitudinal axis as shown in Figure 18. The bag assembly includes a sheath (64) disposed about the bag assembly. Upon folding the bag disclosed by Pagedas into a furled position, the folds include at least one transverse fold extending from the first edge toward the second edge such that an angle less than 90 degrees is defined relative to the longitudinal axis (Figure 17). Although Pagedas discloses features of Applicant's invention as described above, the Pagedas reference does not specifically disclose the sheath being fabricated from a flexible heat-shrinking polymer. Summer discloses a sheath fabricated from a flexible heat-shrinking polymer. It would have been obvious to one having ordinary skill in the art at the time the Applicants' invention was made to modify a tissue removal device and method, similar to that disclosed by Pagedas, to include a sheath made from a heat-shrinking polymer, similar to that disclosed by Summer, to allow the sleeve to assume other shapes including a bent shape if desired.

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5. Claims 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cochran et al. (U.S. Patent Number 5,215,521) in view of Kammerer et al. (U.S. Patent Number 5,480,404), in further view of Pagedas (U.S. Patent Number 6,387,102) and in view of Snow et al. (U.S. Patent Number 6,402,722).

In regard to claims 10 and 11, the combined references of Cochran et al., Kammerer et al. and Pagedas disclose the features of the Applicant's invention as described above. The combined references do not disclose including a cord operatively connected to the tear line for facilitating the tearing of the sheath. Snow et al. disclose a cord (18) operatively connected to a tear line for facilitating the tearing of a sheath along the tear line. It would have been obvious to one having ordinary skill in the art at the time the Applicants' invention was made to modify a tissue removal device and method, similar to that disclosed by the combined references of Cochran et al., Kammerer et al. and Pagedas, to include a cord operatively connected to the tear line, similar to that disclosed by Snow et al., to have better control over when the sheath is separated from the rest of the device.

6. Claims 33-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pagedas (U.S. Patent Number 6,387,102).

In regard to claims 33-35, upon use Pagedas discloses method steps including providing a minimally invasive tissue removal device having a bag assembly including an elongated shaft wand (12) with a rod (18) attachment, and a bag (50) connected to the rod (18) and wand (12). The elongate shaft (12) has a distal end and a proximal end, wherein the elongate shaft defines a longitudinal axis. Pagedas further discloses a handle connected to a flexible bag support (22) defining an opening, the bag support (22) being collapsible and expandable to open and close the

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opening. The device includes the bag (50) operatively connected to the bag support. The bag (50) has an open first end operatively secured to the bag support and a closed end. The bag support in a collapsed position substantially closes the first end of the bag. The bag (50) extends away from the wand when in an unfolded position and folds onto itself in a folded position. The Pagedas device has folds approximately parallel with the longitudinal axis as shown in Figure 18. The bag assembly includes a sheath (64) disposed about the bag assembly. Upon folding the bag disclosed by Pagedas into a furled position, the folds include at least one transverse fold extending from the first edge toward the second edge such that an angle less than 90 degrees is defined relative to the longitudinal axis (Figure 17). Pagedas submits it would be desirable to fold the bag assembly suit the purpose of use, while avoiding the addition of stresses which may compromise the durability of the bag. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the collapsing and folding of the bag because one of ordinary skill in the art would have expected such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Pagedas.

Response to Arguments

7. Applicant argues the prior art references do not disclose having a collapsible bag which folds onto itself. Examiner submits the prior art references disclose a collapsible bag retrieving member which is capable of collapsing by folding onto itself, however this feature is not specifically disclosed by the Cochran et al. and Kammerer et al. prior art references. Examiner further submits it would be obvious to try various folds to collapse and maneuver the retrieving

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member. Nonetheless, Examiner has introduced a reference which teaches folding the retrieving member onto itself upon maintaining the device in a folded position. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fangemonique Smith whose telephone number is 571-272-8160. The examiner can normally be reached on Mon - Fri 8am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

FS

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736